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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,119	03/19/2001	Michael J. O'Connor	MICRU: 56212	2506

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EXAMINER

FARAH, AHMED M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/18/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/813,119

Applicant(s)
O'Connor et al.

Examiner
Ahmed M. Farah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 24, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5-10, 12-14, 16-21 and 23 are again rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al. U.S. Pat. No. 6,063,080.

As to claims 1-3, 6, 8, 12-14 and 17, Nelson et al. disclose a variable stiffness heating catheter 12 for use in interventional vascular therapy, comprising:

a heating catheter shaft (hollow shaft 50; see Fig. 5) having a proximal end and a distal end 14, said heating catheter shaft including at least one electrically conductive element (tabular electrode 18 and/or guide wire 80); and

reinforcing tubes (coaxial tubes 40, 52, 54 and electrode 18; see Fig. 5 and Col. 6, lines 1-34) attached to the heating catheter shaft (hollow shaft 50 which incloses RF electrode 18 and guide wire 80), the heating catheter shaft extending through the reinforcing tubes (heating

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electrode **18** and guide wire **80**, which extend through hollow tubes **40**, **52** and **54**), wherein at least one of said reinforcing tubes has a surface defining a plurality of apertures (micro-apertures **84**) to provide variation in stiffness along the length of the heating catheter shaft (see Fig. 4 and Col. 7, lines 49-52).

As to claims 5, 7, 16 and 18, the outer surface of at least one of the reinforcing tube (coaxial tube **40**) has a configuration selected from the set consisting of: a continuous tube having a constant diameter, a continuous tube having a continually tapered diameter, a continuous tube having at least a portion of which has a tapered diameter, a series of tubes of varying degrees of flexibility which are fixed connected together in a coaxial, end-to-end manner,” and any combination thereof. See Col. 6, lines 10-28.

As to claims 9 and 20, the outer tube of their catheter is constructed of a nylon (Merriam Webster’s Collegiate Dictionary defines nylon as any of a family of high-strength, resilient synthetic polymers, the molecules of which contain the recurring amide group CONH). See Col.4, lines 59-62.

As to claims 10 and 21, Fig. 3 of Nelson et al. clearly shows that the catheter body **12** is sealed by pressure fit or heat shrinking (Col. 6, lines 63-67).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 4 and 15 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. in view of Mueller U.S. Pat. No. 4,801,297.

Although Nelson et al., described above, form lateral slits (micro-apertures 84) on the outer surface of their catheter to increase its flexibility, they fail to teach the use of helical slits as presently claimed.

However, Mueller teaches a flexible medical catheter **10** having a plurality of axial slits **20** and a plurality of helical slits **28** disposed on the outer surface of the catheter body **12** so as to increase the flexibility of the catheter tip **24** (Fig. 1; Col. 1, lines 64-67; and Col. 2, lines 15-20). The increase in flexibility enables the catheter to bend very easily within a body lumen thereby reducing the risk of arterial wall puncture and damage.

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Nelson et al. with Mueller and form helical and/or axial slits on the outer surface of the catheter body in order to increase its flexibility. Since these are not critical, provide no unexpected results, the helical and/or axial slits would have been an

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equivalent alternative pressure release to the lateral slits of Nelson et al.

4. Claims 11 and 22 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. in view of Nardella U.S. Pat. No. 5,334,193.

Although Nelson et al., described above, teach that the outer body of their catheter is made of polymer (nylon), their polymer is not selected from the group consisting of polyethylene, polytetrafluoroethylene, polyetherethulketone or polyphenylenesulfide as presently claimed.

However, Nardella discloses an electrosurgical catheter manufactured of flexible, biocompatible polymer, such as polyolefins, nylons, or polytetrafluoroethylene. He further teaches that the use, compatibility, and/or interchangeability of the different polymers are well known in the art of manufacturing medical catheters (Col. 5, lines 12-21). Thus, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Nelson et al. in view of Nardella to have a catheter body manufactured of polytetrafluoroethylene polymer. Furthermore, it is known in the art that the flexible polymeric materials such, polyethylene, polyvinylchloride, or polytetrafluoroethylene behave as heat resistant when an electric potential is applied across them.

Response to Arguments

4. Applicant's arguments filed on March 2, 2003 have been fully considered but they are not persuasive. The applicant argues that "the shaft 50 does not enclose electrode 18." He further

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implies that the heating catheter shaft of Nelson et al. does not include at least one eclectically conductive member as recited in the independent claims 1 and 13.

In response to these arguments, the applicant's independent claims 1 and 13 recite that 'the heating catheter shaft includes at least one electrically conductive member.' However, neither of the claims teaches or suggests^s that the electrically conductive element is used to provide heat and/or electrical energy to the desired treatment site. Therefore, the examiner's position is that both the electrode 18 or the guide wire 80 are eclectically conductive elements enclosed within the catheter shaft. For example, if the electrode 18 is treated as a reinforcing tube having a plurality of apertures to provide variations in the stiffness along the length of the heating catheter shaft, the guide wire 80~~is~~ would be treated as an electrically conductive member enclosed within the reinforcing tube, as presently claimed. The applicant is advised to clarify the functions of the electrically conductive element recited in the claims.

The applicant further argues that 'Nelson et al. fail to teach or disclose microapertures, which provide variations in stiffness along the length of the heating catheter as recited in the claims.' In response to this argument, column 7, lines 49-52 of Nelson et al. clearly teach that the mico-apertures 84 increase flexibility of the catheter. In this Office Action, the increase in flexibility of Nelson's catheter is viewed as being analogous to the change/variation in stiffness of the catheter as presently claimed.

As to claims 4 and 15, the applicant argues that Mueller teaches 'a rounded or oval lateral apertures, and therefore fails to show helical and/or axial slits as presently claimed.' In response

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to this argument, Fig. 1 of Mueller clearly teaches axial/lateral slits 20 to vary the stiffness of the catheter. As to the helical slits in claim 15, the applicant's disclosure fails to teach the criticality of the helical apertures. Therefore, since Applicant's written description fails to that the use of helical slits is critical, has a particular advantage and/or provides unexpected results, the Examiner's position is that the use of helical and/or axial apertures would have been an equivalent alternative pressure release to the lateral slits of the prior art.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,556,873 B1 to Smits; U.S. Patent No. 5,356,388 to Sepetka et al.; and U.S. Patent No. 5,972,026 to Laufer et al., disclose variable stiffness catheter devices comprising at least one conductive element and a reinforcing tube having helical slits.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The official fax number for the group is (703) 872-9302; and the fax number for After Final is (703) 872-9303.

A. M. Farah

Patent Examiner (Art Unit 3739)

June 14, 2003

A handwritten signature in black ink, consisting of a stylized 'L' and 'D' intertwined.

Linda C.M. Dvorak

Supervisory Patent Examiner